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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,299	03/12/2004	James F. McGuckin JR.	1231	8233
7590 NEIL D. GERSHON REX MEDICAL 1011 HIGH RIDGE RD Stamford, CT 06905		07/13/2007	EXAMINER EREZO, DARWIN P	
			ART UNIT 3731	PAPER NUMBER
			MAIL DATE 07/13/2007 DELIVERY MODE PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/800,299	MCGUCKIN ET AL.
	Examiner Darwin P. Erez	Art Unit 3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 April 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4,6-13 and 15-18 is/are pending in the application.
 - 4a) Of the above claim(s) 17 and 18 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,4,6-13,15 and 16 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 March 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/18/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 6/18/07 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

2. Claim 9 is objected to as being of improper dependent form for failing to further limit the subject matter of a previous claim since the claim depends on a cancelled claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. When treating the claim on the merit, the claim will be considered to be a dependent claim of claim 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 3731

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1, 2, 4, 6-13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,146,396 to Konya et al. to US 6,425,909 to Dieck et al.

(claim 1) Fig. 5 of Konya discloses a device that is fully capable of providing distal protection, the device comprising a catheter **12** and clips **32**, which is being interpreted as a "combined catheter" or a tubular device. This combined catheter includes a side wall (the end portion) having a slot opening in which flexible members **30** move from a first retracted position (Fig. 1) to a second looped position (Fig. 5). It is noted that the applicant does not specifically recite the location of the sidewall, whether the sidewall is parallel to the longitudinal axis of the catheter, or whether the sidewall is the end portion wall of the catheter.

Flexible members **30** is also disclosed as forming first and second loop openings that extends laterally with respect to the catheter such that a first loop opening extends perpendicular to the longitudinal axis of the catheter (see Fig. 5). There is also a mesh deformable jacket **16**, which is being interpreted as a filtering material because a mesh structure is fully capable of being used as a filter. Furthermore, the filtering material is also movable from collapsed position to an expanded position (col. 3, lines 57-60).

Konya discloses all the limitation of the claim except for the flexible member being a single element and not a plurality of elements.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the flexible member a unitary element, since it has been held that forming in one piece an article which was formerly formed in multiple

pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Furthermore, Dieck discloses a similar expanding distal device, in which a single flexible wire is used to provide multiple loop openings (see Figs. 1 and 2). This flexible wire is an equivalent structure known in the art since either structure of Konya or Dieck or used for expanding the device. Therefore, since these two elements are art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute one element for the other element.

(claim 2) The flexible material is contained within the catheter in the first position (Fig. 1 or 6).

(claim 4) The flexible member loops in a plane perpendicular to the longitudinal axis of the catheter (Fig. 5).

(claims 6 and 7) Konya discloses a second loop **30** radially spaced from the first loop, wherein the loops extend in opposite directions approximately 180 degrees apart. (Fig. 5).

(claims 8 and 9) The loops are axially offset with respect to a transverse axis of the catheter.

(claim 10) Actuating member **14** moves the flexible member into a looped position.

(claim 11) Movement of the actuating member to a retracted position would automatically move the filtering material to a collapsed position, as seen in Fig. 1.

Art Unit: 3731

(claim 12) See the rejection to claim 1 and the following: wire 33 has a portion that loop distally and a portion that loops proximally.

(claim 13) See the rejection to claim 10.

(claim 15) See the rejection to claims 1 and 11 and the following: the loop opening defined by loops 33 lies in a plane that is non-aligned with the longitudinal axis of the catheter. Also see col. 3, lines 57-60.

(claim 16) See the rejection to claim 1.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 2, 4, 6-13, 15 and 16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Darwin P. Erez
Examiner
Art Unit 3731

de

Jackie Tan-Uyen Ho
(JACKIE) TAN-UYEN HO
SUPERVISORY PATENT EXAMINER

7/9/07